



Certificate

No. Q5 074544 0012 Rev. 03

Holder of Certificate: **URIT Medical Electronic Co., Ltd.**

No. D-07
Information Industry District
High-tech Zone
541004 Guilin, Guangxi
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of In Vitro Diagnostic Reagents for Clinical Chemistry, Immunochemistry, Hematology, Infectious Diseases and Sample Processing, In Vitro Diagnostic Calibrators and Control Materials for Clinical Chemistry; Design and Development, Production, Distribution, Installation and Servicing of In Vitro Diagnostic Instruments for Clinical Chemistry, Immunochemistry, Hematology and Sample Processing; Design and Development, Production and Distribution of Ultrasonic Scalers, High-Speed Turbine Dental Handpieces, LED Light Curing Device and Ultrasonic Scaler Tips

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 074544 0012 Rev. 03

Report No.: GZ2316301

Valid from: 2023-10-17

Valid until: 2026-09-13

Date, 2023-10-18

Christoph Dicks
Head of Certification/Notified Body

Certificate

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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **URIT Medical Electronic Co., Ltd.**
No. D-07, Information Industry District, High-tech Zone, 541004 Guilin,
Guangxi, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production of In Vitro Diagnostic Reagents for
Clinical Chemistry, Immunochemistry, Hematology, Infectious Diseases
and Sample Processing, In Vitro Diagnostic Calibrators and Control
Materials for Clinical Chemistry;
Design and Development, Production of In Vitro Diagnostic Instruments
for Clinical Chemistry, Hematology and Sample Processing;
Warehousing

URIT Medical Electronic Co., Ltd.
No. D-02, Information Industry District, High-tech Zone, 541004 Guilin,
Guangxi, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Ultrasonic
Scalers, High-Speed Turbine Dental Handpieces, LED Light Curing
Device, Ultrasonic Scaler Tips;
Distribution of In Vitro Diagnostic Reagents for Clinical Chemistry,
Immunochemistry, Hematology, Infectious Diseases and Sample
Processing, In Vitro Diagnostic Calibrators and Control Materials for
Clinical Chemistry;
Distribution, Installation and Servicing of In Vitro Diagnostic Instruments
for Clinical Chemistry, Immunochemistry, Hematology and Sample
Processing

URIT Medical Electronic Co., Ltd.
NO.4 East Alley, Jiuhua Road, 541001 Guilin, Guangxi, PEOPLE'S
REPUBLIC OF CHINA

Design and Development, Production and Distribution of In Vitro
Diagnostic Instruments and Reagents for Clinical Chemistry of Rapid
Tests

URIT Medical Electronic Co., Ltd.
1F & 2F of Building No.1, Building No.2, No. GX-G08, East Side of
Donghuan Road, Qixing District, 541004 Guilin, Guangxi, PEOPLE'S
REPUBLIC OF CHINA

Design and Development, Production of In Vitro Diagnostic Instruments
for Clinical Chemistry (Automatic Chemistry Analyzer and Electrolyte
Analyzer) and Immunochemistry (Chemiluminescent Immunoassay
Analyzer)